deemed rejected under 35 U.S.C. §103(a) as being unpatentable over Dardik et al '526, Pratt et al, Lau et al, and Chin.

Brendel discloses an allograft suitable for implantation. The gist of the Brendel disclosure is to derive whole structures in the form of an extra cellular matrix from which cellular membranes, nucleic acids, lipids, and cytoplasmic components have been removed. To achieve this result, Brendel describes the isolation of a human umbilical cord which are cannulated at the umbilical vein. The cords are then treated with a pair of detergents. The first detergent is employed to remove cytoplasmic cell membranes. A second detergent follows the first detergent and is used to dissolve nuclear membranes. A washing step intercedes the use of the first and second detergents. The object of the detergent is to provide a non-antigenic structure to repair living body parts. Brendel does not describe the use of vessels derived from umbilical cords. Most importantly, Brendel does not employ lyophilization for the purpose of producing an elastic vessel with low antigenicity. Lyophilization is mentioned as a method after though used to maintain the vessel in a sterile condition. However, it is asserted that the removal of the cytoplasmic cell and nuclear membranes with the dual detergent treatment significantly weakens the umbilical cord sheath and would do the same for a vessel, if it were isolated from an umbilical cord. In fact, Brendel admits that the elastine remaining after the dual detergent treatment is somewhat lower than collagens, except in ligaments. In any case, the extra cellular matrix formed by the Brendel amounts to a denaturing or tanning of the body part. Such characteristic is lacking in Applicant's

claimed human umbilical and placental vessels which does not suffer from such alteration of the natural structural integrity.

Dardik employs the vessels from the umbilical cord for use in a tubular prosthesis in vascular reconstructive surgery. However, the vessel is shaped by a mandrel and soaked in a glutaraldehyde solution to harden the vessel. Thus, the vessel is made rigid through this denaturing or tanning procedure. Following the tanning, a polyester mesh is applied to the graft for added support. Through the Dardik procedure, a graft, which is rigid and non-elastic, is obtained. This is because the integrity of the vessel wall has been destroyed using the Dardik procedure. Dardik does describe the possibility of lyophilizing the vessel however this occurs to preserve the vessel or to sterilize the vessel following Dardik treatment to remove antigenicity. Dardik does not recognize Applicant's vessel structure which is directly lyophilized without chemical denaturing.

Pratt describes the freeze-drying of rat vessels but does not teach the use of human placental or umbilical vessel. In fact, the reference to Chow, page 628 of Pratt, teaches away from Applicant's invention stating that a heterograft according to the Chow study would not make a good vascular substitute due to stronger immune reactions that would be found in an allograft.

Chin describes the use of a graft-stabilizing catheter for eventual use with a balloon cannula to secure the graft to a target tissue. Chinn does not disclose the production of an allograft isolated from human placental or umbilical cords.

Lau describes a polyamide stent which may be used in combination with umbilical derived tissues. Lau uses a foldable stent which is eventually expanded by the use of an angioplasty balloon. Again, Lau does not describe the production of a preserved vessel isolated from human umbilical cords or placentas.

Applicant was the first to recognize and devise a production of a preserved vessel isolated from a human umbilical cord or placenta, which uses direct lyophilization without chemical denaturing. It is asserted that chemical denaturing weakens the elasticity and integrity of the walls of the vessel, as described in the Brendel and Dardik references. In fact, Duardik recognizes this fact and reinforces the weakened vessel with hardening agents and mesh structures. The vessels produced by the Brendel or Dardik references do not exhibit the wall integrity and elasticity found in Applicant's vessels, since the natural wall structure in Applicant's vessel has not been altered by denaturing chemicals. The addition of Pratt to the Dardik and Brendel references would, as is recognized by the Brendel reference, only sterilize or preserve the vessel which has be radically altered through either the Brendel or Dardik chemical treatments. Lau and Chin show stents which are used for angioplasty purposes. Applicant uses a stent to maintain the walls of vessels, isolated from umbilical cords and placentas, merely for the purpose of preserving the lumen of the vessel during the lyophilization process. Thus, the invention disclosed by the references taken alone or in combination would still not result in a vessel claimed by Applicant, which possesses a wall integrity closely resembling that of the original vessel.

It is believed that the application as amended is now in condition for allowance and the passing to issue of the application at an early date is earnestly solicited.

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